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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,868

09/30/2003

Michael Slivka

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7650

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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,868

Applicant(s)

SLIVKA ET AL.

Examiner

Leon Lankford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

The current application contains claims directed to a plurality of distinct species; in order to expedite prosecution, it is required that applicants elect a single species from each of the disclosed groups listed below for initial examination.

1. **Type of Repair Material** (claims 1, 4, 5 & 13 are considered to be generic):

Bioresorbable; Non-bioresorbable.

Upon election of **Bioresorbable** Repair Material, a single species of bioresorbable material must be elected, the species are as follows:

Small intestine submucosa (SIS); collagen; hyaluronic acid; elastin; albumin; reticulin; synthetic polyamino acids; prolamines; polysaccharides; alginate; heparin; biodegradable polymers of sugar units; polylactide; polyglycolide; polydioxanone; polyhydroxybutyrate; polyhydroxyvalerate; poly(propylene fumarate); polyoxaesters; biodegradable polyurethanes and their copolymers.

Upon election of **Non-Bioresorbable** Repair Materials, a single species of non-bioresorbable material must be elected, the species are as follows:

Polyacrylates; ethylene-vinyl acetates; acyl-substituted cellulose acetates besides ethylene-vinyl acetate; polyester; poly(ethylene terephthalate); polypropylene; polyethylene; polyurethanes; polystyrenes; polyvinyl oxides; polyvinyl fluorides; poly(vinyl imidazoles); chlorosulphonated polyolefins; polyethylene oxides; polyvinyl alcohols (PVA); polytetrafluoroethylenes; nylons.

2. **Type of Cells Seeded in Cell-Seeded Material** (claims 1 and 17 are generic):

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stem cells; bone marrow cells; fibrocytes; adipocytes; chondrocytes; cells harvested from spinal discs in the body; nucleus pulposus cells; annulus fibrosis cells.

3. Type of Autologous Medium to be Combined with Material (claims 1 and 20 are generic):

platelet-rich plasma; platelet-poor plasma; bone marrow; whole blood; serum

4. Type of Bioactive Factor to be Combined with Material (claims 1, 23, 26, 29, 32, 35, 38 are generic):

TGF- β 1; TGF- β 2; TGF- β 3; GDF-5; MP52; BMPs; platelet derived growth factor (PDGF); fibroblast growth factors (FGFs); insulin-like growth factors (IGFs); protein polymers; RGD-peptides; Indian Hedgehog proteins; anti-inflammatory agents; angiogenic factors; hormones; hyaluronic acid.

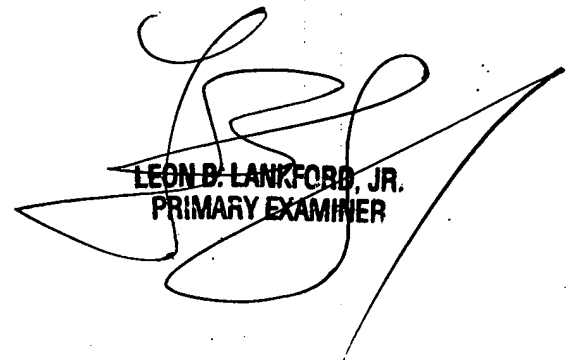
The species in each group above are independent or distinct because none of the species are automatically rendered obvious by the others in its group as they are not all art recognized equivalents. Additionally, the disclosure does not connect every species of each of the above described genres by design, structure, operation, or effect. See M.P.E.P. § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required. See M.P.E.P. § 808.01(a). In this case, considering enablement, utility, and description issues for each claimed species, as well as conducting a thorough search of the prior art for each and every combination embodied by the present claims, would pose a serious burden to the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the FOUR groups above, even though this requirement is traversed. Applicant is advised that a reply to this

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requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).



LEON B. LANKFORD, JR.
PRIMARY EXAMINER